

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized;

creating a subcutaneous tunnel having a first end and a second end, wherein [a] the first end of the subcutaneous tunnel is near the incision near the area to be catheterized;

131 routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through the second end of the subcutaneous tunnel; and

attaching the proximal portion of the hub body to the distal portion of the catheter tube.

REMARKS

Claims 1-15 are pending in the application.

Claims 7-13 are allowed.

Claims 1-6 are objected to under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1, 14 and 15 are rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,624,413 to Markel. Additionally, claims 1, 14 and 15 are rejected under 35 U.S.C. §103(a) as unpatentable over Markel in view of U.S. Patent No. 4,772,268 to Bates.

Claims 2-6 are objected to as being dependent upon a rejected base claim.

Applicant has amended Claim 1 so as to more distinctly claim the subject matter which the Applicant regards as the invention. Thus, Applicant requests the rejection of claims 1-6 under 35 U.S.C. §112, second paragraph be withdrawn.

As to the 35 U.S.C. §103 obviousness rejections, Applicant respectfully traverses the rejections because the Office Action fails to establish a *prima facie* case of obviousness. There is no suggestion or motivation in the references for the modification or combination. Absent such a suggestion or motivation in the primary reference for the modification or combination of references, such a modification or combination is improper.

The Examiner makes two statements regarding the Markel et al. reference. First:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the catheter tubes (22) and (24) of Markel et al. into a multi-lumen catheter tube, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1983).

p. 3 of the Office Action. Second:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Bates into the invention of Markel et al. by modifying the catheter tubes (22) and (24) of Markel et al. as such, in order to minimize the amount of incision to one instead of two different incisions into an are to by catheterized.

p. 4 of the Office Action.

The MPEP clearly states that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no

suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The modification of the Markel patent suggested by the Examiner would clearly render the device of Markel unsatisfactory for its intended purpose. The Background of the Invention in the Markel patent discusses the various disadvantages of multi-lumen catheters and advantages afforded by assemblies of single lumen catheters, A.K.A. "Tesio catheters", concluding:

However, dual lumen catheters suffer from the same disadvantages as the Tesio double catheter assembly highlighted above in that one lumen cannot be replaced independently of the other lumen. Many dual lumen catheters also have poor flow characteristics due to the shape and size of the individual lumens.

Thus, there is a need in the art for a simple method of catheterization which requires only one procedure, which takes advantage of the benefits provided by Tesio [single lumen] catheters, and which does not suffer from the shortcomings of the methods highlighted above. The present invention fills such a need.

Col. 2, lines 20-32. The Summary of the Invention states, in pertinent part:

The present method provides a method for inserting *a multiple catheter assembly* into an area of a body to be catheterized. The assembly comprises *a first and a second catheter*, each catheter having a distal portion and a proximal portion. . . . The first and second catheters are independently movable with respect to each other, or unattached to each other, along their entire length. The method includes the steps of . . . adjusting a longitudinal distance between the proximal portions of the first and second catheters to provide a predetermined longitudinal distance between the distal portions of the first and second catheters within the area . . .

Col. 2, lines 35-50 (emphasis added). Additionally, throughout the Detailed Description of the Preferred Embodiment the advantages of a multiple catheter Tesio-type assembly

over a multi-lumen catheter are discussed repeatedly. For example Col. 6, lines 24-28 (the offset between the tips of the two catheters “d” is easily modified with two unconnected catheters); Col. 6, lines 53-57 (high flow rates collapse lumens in multi-lumen catheters which would not collapse in a single lumen catheter; higher flow rate equates to shorter procedure time for a patient); Col. 6, lines 62-67 (longer “d” and ability to independently move catheters help prevent recirculation of blood); and Col. 7, lines 14-29 (“important feature of the invention is that before, during and after insertion . . . first and second catheters 22, 24 are independently movable with respect to each other”; removal and replacement of one catheter can be performed independently and without interfering with other catheter).

The modification of Markel in the way suggested by the Examiner, i.e. substitution of a multi-lumen catheter for single lumen catheters, would necessarily render the Markel patent unsatisfactory for its intended purposes. This being the case, there is no suggestion or motivation to make the proposed modification.

In addition to the reason given above, the motivation presented by the Examiner for combining the catheters of Markel into a multi-lumen catheter of the type disclosed by Bates is that Bates requires only a single incision while Markel requires more than one incision. This motivation is not supported by the disclosure of the Markel patent because Markel only discusses a single incision for entry of all of the catheters. See, e.g., Col. 2, lines 44-46 and Col. 7, lines 30-31 and 42-47.

Given the above reasons, the Applicant submits that a *prima facie* case of obviousness regarding claims 1, 14 or 15 cannot be presented utilizing the Markel patent, either alone or in view of Bates.

In view of the above amendment and remarks, reconsideration of the rejection and allowance of all claims is respectfully requested.

If an extension of time is required to enable this document to be timely filed and there is no separate Request for Extension of Time, this document is to be construed as also constituting a Request for Extension of Time Under 37 C.F.R. § 1.136(a) for a period of time sufficient to enable this document to be timely filed. Any fee required for such a Request for Extension of Time and any other fee required by this document pursuant to 37 C.F.R. §§ 1.16 and 1.17 and not submitted herewith should be charged to the Deposit Account of the undersigned attorneys, Account No. 01-1785; any refund should be credited to the same account. One copy of this document is enclosed.

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